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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,613	04/19/1999	KOICHI ISHIGURO	1416/OP551PC	2418
7590 03/04/2004				
WENDEROTH LIND & PONACK 2033 K STREET NW SUITE 800 WASHINGTON, DC 20006		EXAMINER GUCKER, STEPHEN		
		ART UNIT PAPER NUMBER		

1647

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/142,613

Applicant(s)

ISHIGURO ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) 1,6,8, & 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Claims 9 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. ("Sato", Peptide Chemistry 1994) in view of Ishiguro et al. ("Ishiguro", Neurosci Lett. 202, 1995) for reasons of record and the following. Sato discloses that paired helical filaments (PHFs) accumulate in the neuron of AD brain and highly phosphorylated tau protein was found to be a component of PHFs. Also, Sato discloses instant SEQ ID NO:2 as a phosphorylated fragment of tau protein and suggests making antibodies against SEQ ID NO:2 (pages 109 and 112). Sato does not disclose that antibodies raised against SEQ ID NO:2 would not bind to non-phosphorylated SEQ ID NO:2. Ishiguro discloses antibodies against instant SEQ ID NO:2 that do not react to non-phosphorylated SEQ ID NO:2 (Figures 1-3). Ishiguro also teaches that PHFs are a hallmark of AD and that PHFs contain highly phosphorylated tau protein (page 81). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibodies suggested or made in the references to diagnose AD because both references teach that highly phosphorylated tau protein occurs in AD and antibodies that bind specifically to phosphorylated tau protein fragments but do not bind

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to non-phosphorylated tau protein fragments (as in the Ishiguro reference) would be *prima facie* obvious to use for the diagnosis of AD because a hallmark of AD is that PHFs contain highly phosphorylated tau protein.

*Applicant's arguments filed 11/3/03 have been fully considered but they are not persuasive. Applicant argues that the Sato and Ishiguro references do not disclose a reactivity of the antibody with a brain or CSF sample of an individual having AD. This is true, for if the references did teach using a brain or CSF sample from an individual having AD with the antibodies that the references do disclose, the references would have anticipated the instant invention and a rejection would have been made under USC 102. However, the combined references render the instant invention obvious for the reasons of record set forth above for the motivational reasons presented in the prior Office Action. It would have been prima facie obvious to use brain or CSF samples from individuals suspected of having AD with the methods and antibodies of the combined references to provide a more definitive biochemical diagnosis of AD since there is no biochemical test presently in existence that can accurately diagnose AD in an individual. A current diagnosis of AD relies mostly on behavioral observations more than any other single factor.*

4. It is noted by the Examiner that either the Sato or the Ishiguro references listed above would be held as prior art against any of the claims drawn to the antibody product produced by using SEQ ID NO:2 as an immunogen.

5. No claim is allowed.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

March 2, 2004

*Gary d. Kunz*

GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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